K093978 MAY 11 2010

Exactech® Equinoxe® Proximal Humerus Fracture Plate System
Traditional 510(k)

510(k) Summary

Company:	Exactech®, Inc
Date:	December 22, 2009
Contact Person:	Shing Jen Tai, PhD Regulatory Affairs Specialist
Proprietary Name:	Exactech® Equinoxe® Proximal Humerus Fracture Plate System
Common Name:	Proximal Humerus Fracture Plate
Classification Name:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories (21 CFR 888.3030, Class II, Product Code KTW)

Legally Marketed Devices to Which Substantial Equivalence Is Claimed

- Synthes LCP® Proximal Humerus Plate (#K011815)
- Synthes (USA) LCP® Proximal Humerus Plates, Long (#K041860)
- Hand Innovations Modified Shoulder Fixation Systems (#K042059, #K051728, #K060290)

Device Description

The Equinoxe® Proximal Humerus Fracture Plate System is for use in the repair of proximal humerus fractures. The system consists of the following components. With the exception of blade locking screws, all components are provided in various sizes.

- Proximal Humerus Fracture Plates
- Locking Screws, Cancellous and Cortical

- Humeral Blades
- Blade Locking Screws
- Compression Screws, Cortical

Made of 316L Stainless Steel (per ASTM F138-08), all components are supplied non-sterile and must be sterilized in a provided re-usable sterilization container, prior to

implantation. Cleaning and Sterilization instructions are provided in the package insert for the Equinoxe® Proximal Humerus Fracture Plate System.

Indications for Use
The Equinoxe® Shoulder Proximal Humerus Fracture Plate System is indicated for Open Reduction Internal Fixation (ORIF) procedures of the proximal humerus. Clinical indications are as follows:

- Fractures, fracture dislocations, osteotomies, and non-unions of the proximal humerus.

Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use.** Similar to the intended uses for its predicate devices, the Equinoxe® Proximal Humerus Fracture Plate System is intended to be used for internal fixation of fractures, fracture dislocations, osteotomies, and non-unions of the proximal humerus. Equinoxe® Proximal Humerus Fracture Plate System and predicate devices also have similar indications for use statements.
- **Materials.** Equinoxe® Proximal Humerus Fracture Plate System and predicate devices are composed of equivalent materials conforming to recognized industry standards for orthopedic and trauma implants.
- **Dimensions.** Equinoxe® Proximal Humerus Fracture Plate System and predicate device components are available in equivalent size ranges.
- **Sterilization processes.** Equinoxe® Proximal Humerus Fracture Plate System and predicate devices are provided non-sterile and are sterilized prior to implantation, using equivalent sterilization processes conforming to recognized industry standards.
- **Performance specifications.** Equinoxe® Proximal Humerus Fracture Plate System and predicate devices withstand clinically relevant biomechanical loads that are exerted on the humerus during post-operative rehabilitation and fracture healing.

Substantial Equivalence Conclusion
Results from mechanical tests and simulated-use studies provided within this 510(k) premarket notification demonstrate that Exactech® Equinoxe® Proximal Humerus Fracture Plate System is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Exactech, Inc.
% Ms. Shing Jen Tai
2320 N.W. 66th Court
Gainesville, Florida 32653

MAY 11 2010

Re: K093978
Trade/Device Name: Exactech Equinoxe Proximal Humerus Fracture Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: April 16, 2010
Received: April 22, 2010

Dear Ms. Tai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Brehm
for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Equinoxe® Proximal Humerus Fracture Plate System
Traditional 510(k)

Indications for Use Statement

510(k) Number: K093978

Device Name: Exactech® Equinoxe® Proximal Humerus Fracture Plate System

INDICATIONS FOR USE:
The Equinoxe® Shoulder Proximal Humerus Fracture Plate System is indicated for Open Reduction Internal Fixation (ORIF) procedures of the proximal humerus. Clinical indications are as follows:

- Fractures, fracture dislocations, osteotomies, and non-unions of the proximal humerus.

Prescription Use __X__ **and/or** **Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Please do not write below this line – use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093978